INVESTIGATOR FINANCIAL DISCLOSURE

What is required?
Federal regulations require that any actual or potential conflicts of interest that may exist due to financial interest of a principal investigator or project director be disclosed to the IRB as well as the research subject in the informed consent document.

Who must make a disclosure?
“Investigator” means the principal investigator, sub- investigator, and persons at the investigator’s office responsible for design, conduct, or reporting of research, education, or service activities funded, or proposed for funding, by an external sponsor. (For the purposes of disclosing the Investigator’s significant financial interest, the term “Investigator” includes the Investigator’s spouse and dependent children.)

What must be disclosed?
Each investigator shall disclose all significant financial interests:
1. that would reasonably appear to be directly and significantly affected by the research, educational, or service activities funded, or proposed for funding, by and external sponsor; and/or
2. in entities whose financial interests would reasonably appear to be directly and significantly affected by such activities.

“Significant Financial Interest” means anything of monetary value, including, but not limited to salary or other payments for services (e.g. consulting fees or honoraria); equity interests (e.g. stocks, stock options or other ownership interests); and intellectual property rights (e.g. patents, copyrights, and royalties from such rights). The term does not include:
1. salary, royalties or other remuneration from Baptist Medical Center.
2. income from seminars, lectures, or teaching engagements sponsored by public or non-profit entities.
3. income from service on advisory committees or review panels for public or nonprofit entities;
4. an equity interest that when aggregated for the investigator and the investigator’s spouse and dependent children, meets both of the following tests: 1) does not exceed $10,000 in value (or $10,000 per annum if such interests represent salary, fees, or other continuing payments) and 2) does not represent more than 5% ownership interest for any one enterprise or entity.

Disclosure Procedures:
1. Disclosure by the investigator of any significant financial interest is required prior to the submission of a sponsored project proposal. This should be done using the Disclosure of Financial Interests Related to Sponsored Projects Form (Attached).
2. Disclosures of significant financial interests that develop after a proposal is submitted or after an award is received must be made immediately by the investigator to the IRB.
3. Financial disclosures must be updated during the period of the award, either annually or as new reportable significant financial interests develop or are obtained.
4. To the extent permitted by IRB policy and State and Federal laws, all records of financial interest will be maintained confidentially.
5. Violations of this policy will be referred to the Chief Medical Officer for Baptist Medical Center.

It is important to note that the requirements being imposed by the federal government are specifically related only to sponsored project proposals. The IRC’s Conflict of Interest Policy continues to apply fully to all investigator’s under all circumstances.